

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/772,963	02/05/2004	David P. Bingaman	2471 US	5299
7590 06/04/2007 Teresa J. Schultz Alcon Research, Ltd.			EXAMINER	
			HUI, SAN MING R	
6201 South Fre Fort Worth, TX			ART UNIT	PAPER NUMBER
,			1617	
			MAIL DATE	DELIVERY MODE
			06/04/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.



Commissioner for Patents United States Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450 www.uspto.gov

MAILED

JUN 0 4 2007

GROUP 1600

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/772,963 Filing Date: February 05, 2004 Appellant(s): BINGAMAN ET AL.

Teresa J. Schultz
Alcon Research, Ltd.
6201 S. Freeway, Q-148
Fort Worth, TX 76134-2099
For Appellant

EXAMINER'S ANSWER

Art Unit: 1617

This is in response to the appeal brief filed January 18, 2007 appealing from the Office action mailed February 14, 2006(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

5,371,078	Clark et al.	6-1994

Page 3

2-1995

Application/Control Number: 10/772,963

Art Unit: 1617

WO 95/03807 Billson et al.

4,686,214 Boltralik et al. 8-1987

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3-5 and 8-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peyman et al. (US patent 5,516,522) and Clark, Clark is reference of record.

Peyman teaches prednisolone, prednisolone acetate, triamcinolne, fluoromethalone, and fluoromethalone acetate as useful in treating proliferative vitreoretinopathy (PVR), an ocular angiogenesis-associated disorder (See col. 7, lines 33-55, especially lines 50, 51, 54). Peyman also teaches the ocular formulation may be as intraocular implant (See the abstract and claim 1).

Clark teaches anecortave acetate as useful in treating ocular neovascularization condition (See claims 1-5). Clark also teaches the composition can be formulated and administered as intraocular injection (See col. 4, lines 50).

Art Unit: 1617

The references taken together do not expressly teach the incorporation of both the herein claimed steroids and anecortave acetate together in a method of treating angiogenesis disorder such as PVR. The references taken together do not expressly teach the herein claimed dosages.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the herein claimed steroids and anecortave acetate together in a method of treating angiogenesis disorder such as PVR. It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the herein claimed dosage to treat PVR.

One of ordinary skill in the art would have been motivated to incorporate the herein claimed steroids and anecortave acetate together in a method of treating angiogenesis disorder such as PVR since the agents are well-known to be useful in treating PVR or neovascularization individually. Therefore, concomitantly employing both agents in a method for the same indications would be *prima facie* obvious (See *In re Kerkhoven* 205 USPQ 1069 (CCPA 1980)).

Furthermore, one of ordinary skill in the art would have been motivated to employ the herein claimed dosage to treat PVR since the optimization of result effect parameters (dosage range, dosing regimens) is obvious as being within the skill of the artisan.

Claims 1, 4-5, and 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO95/03807('807) and Clark.

Art Unit: 1617

'807 teaches a method of treating neovascular macular degeneration, an ocular angiogenesis disorder, by administration of triamcinolne (See the abstract, claims 22-25). '807 teaches the routes of administration may be intravitreal injection (See page 3, lines 19-25).

Clark teaches anecortave acetate as useful in treating ocular neovascularization condition (See claims 1-5). Clark also teaches the composition can be formulated and administered as intraocular injection (See col. 4, lines 50).

The references taken together do not expressly teach the incorporation of both the triamcinolone and anecortave acetate together in a method of treating angiogenesis disorder such as neovascular macular degeneration. The references taken together do not expressly teach the herein claimed dosages.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate triamcinolone and anecortave acetate together in a method of treating angiogenesis disorder such as neovascular macular degeneration. It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the herein claimed dosage to treat neovascular macular degeneration.

One of ordinary skill in the art would have been motivated to incorporate triamcinolone and anecortave acetate together in a method of treating angiogenesis disorder such as neovascular macular degeneration since the agents are well-known to be useful in treating neovascular macular degeneration individually. Therefore, concomitantly employing both agents in a method for the same indications would be *prima facie* obvious (See *In re Kerkhoven* 205 USPQ 1069 (CCPA 1980)).

Art Unit: 1617

Furthermore, one of ordinary skill in the art would have been motivated to employ the herein claimed dosage to treat neovascular macular degeneration since the optimization of result effect parameters (dosage range, dosing regimens) is obvious as being within the skill of the artisan.

Claims 1, 3 and 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clark and US 4,686,214 ('214).

Clark teaches anecortave acetate as useful in treating ocular neovascularization inflammatory condition (See claims 1-5). Clark also teaches the composition can be formulated and administered as intraocular injection (See col. 4, lines 50).

'214 teaches rimexolone as useful in treating ocular inflammation (See claim 2).

The effective dosage of rimexolone taught as 0.05 to 2.0% (See col. 2, line 59-60).

The references taken together do not expressly teach the incorporation of both rimexolone and anecortave acetate together in a method of treating angiogenesis inflammatory disorder. The references taken together do not expressly teach the herein claimed dosages.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to the incorporation of both rimexolone and anecortave acetate together in a method of treating angiogenesis inflammatory disorder. It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the herein claimed dosage to treat angiogenesis inflammatory disorder.

Art Unit: 1617

One of ordinary skill in the art would have been motivated to the incorporation of both rimexolone and anecortave acetate together in a method of treating angiogenesis inflammatory disorder since the agents are well-known to be useful in treating ocular inflammation individually. Therefore, concomitantly employing both agents in a method for treating ocular inflammation associated with angiogenesis would be *prima facie* obvious (See *In re Kerkhoven supra*).

Furthermore, one of ordinary skill in the art would have been motivated to employ the herein claimed dosage to treat ocular inflammation associated with angiogenesis since the optimization of result effect parameters (dosage range, dosing regimens) is obvious as being within the skill of the artisan.

(10) Response to Argument

There are basically two issues or arguments raised by the appellant. The response is set forth below:

Appellant's arguments on pages 4-9 the Brief filed January 18, 2007 averring the cited prior arts' failure to provide motivation to combine the herein claimed agents in the method of treating ocular angiogenesis disease are not convincing. The Examiner notes that the basis to combine the teachings of the cited prior arts resides on the fact that the herein claimed agents are all well-known to be useful in treating ocular angiogenesis disease individually. Therefore, concomitantly employing both agents in a method for treating the very same ocular disorder would be *prima facie* obvious (See *In re Kerkhoven supra*).

Art Unit: 1617

The second argument from the appellant is regard with the "obvious-to-try" reasoning. Appellant's arguments in pages 4-9 the Brief filed January 18, 2007 averring the Examiner employing "obvious-to-try" standard are not convincing. Since the herein claimed agents are well-known as useful to treat ocular angiogenesis disease individually, absent evidence to the contrary, concomitantly employing both agents in a method for treating the very same ocular disorder would be *prima facie* obvious (See *In re Kerkhoven* 205 USPQ 1069). At least additive therapeutic effect is reasonably expected.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

The Information Disclosure Statement filed July 25, 2006 have been considered.

Respectfully submitted,

San-ming Hui Primary Examiner Art Unit 1617

Conferees:

Sreeni Padmanabhan, Ph.D. SPE Art Unit 1617

Johann Richter SPE Art Unit 1616

Art Unit: 1617

The second argument from the appellant is regard with the "obvious-to-try"

reasoning. Appellant's arguments in pages 4-9 the Brief filed January 18, 2007 averring

the Examiner employing "obvious-to-try" standard are not convincing. Since the herein

claimed agents are well-known as useful to treat ocular angiogenesis disease

individually, absent evidence to the contrary, concomitantly employing both agents in a

method for treating the very same ocular disorder would be prima facie obvious (See In

re Kerkhoven 205 USPQ 1069). At least additive therapeutic effect is reasonably

expected.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

The Information Disclosure Statement filed July 25, 2006 have been considered.

Respectfully submitted.

San-ming Hui

Primary Examiner

Art Unit 1617

Conferees:

Sreeni Padmanabhan, Ph.D.

SPE Art Unit 1617

Page 8

SPE Art Unit 1616